



THOMAS L. GARTHWAITE, M.D. Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES 313 N. Figueroa, Los Angeles, CA 90012 (213) 240-8101

October 6, 2005

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

# APPROVE ACCEPTANCE OF AWARD AGREEMENT NO. ID04-LAC-028 FROM THE REGENTS OF THE UNIVERSITY OF CALIFORNIA - UNIVERSITYWIDE AIDS RESEARCH PROGRAM

(All Districts) (3 Votes)

#### IT IS RECOMMENDED THAT YOUR BOARD:

- 1. Approve and instruct the Director of Health Services, or his authorized designee, to accept and sign Agreement No. ID04-LAC-028 (Exhibit I), from the Regents of the University of California Universitywide AIDS Research Program to support a "Screening for Acute HIV Infection in High Risk Men in Los Angeles County" project, effective June 1, 2005 through May 31, 2007, in the amount of \$113,250.
- 2. Delegate authority to the Director of Health Services, or his authorized designee, to accept and sign any forthcoming amendments, substantially similar to Agreement No. ID04LAC-028, that either provide for the extension of the term, rollover of unused funds, and/or which add additional funds that do not exceed 30% of the total dollar amount of the base award, to provide continued funding support for a "Screening for Acute HIV Infection in High Risk Men in Los Angeles County" project, upon review and approval by County Counsel and notification of the Board offices.

#### PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTION:

In approving the recommended actions, the Board is allowing the Department of Health Services' (DHS or Department) Sexually Transmitted Disease (STD) Program to accept funding in the amount of

Gloria Molina First District

Yvonne Brathwaite Burke Second District

> Zev Yaroslavsky Third District

Don Knabe Fourth District

Michael D. Antonovich Fifth District The Honorable Board of Supervisors October 6, 2005 Page 2

\$113,250 to conduct a "Screening for Acute HIV infection in High Risk Men in Los Angeles County" project, from June 1, 2005 through May 31, 2007.

Persons receiving HIV testing through current standards may receive a negative result despite being HIV infected. Believing that they are HIV infection free, these persons with primary HIV may continue to engage in high risk behaviors increasing the risk of HIV transmission during a period of maximum infectiousness. Recent increases in sexual risk behaviors among men who have sex with men have been borne out by a rising HIV and syphilis rate. Acceptance of funding will allow DHS' STD Program to determine the extent to which primary HIV infection in the pre-seroconversion period is missed through current HIV testing measures by maximizing HIV Ribo-Nucleic Acid (RNA) testing using a specimen pooling technique, and then taking appropriate measures to ensure more accurate HIV testing.

# FISCAL IMPACT/FINANCING:

Total program costs to conduct the project, for the period of June 1, 2005 through May 31, 2007, is approximately \$166,237, offset by \$113,250 in funds from the Regents of the University of California - UARP and \$52,987 in DHS in-kind medical laboratory testing resources. Funding is included in the Fiscal Year (FY) 2005-06 Final Budget and will be requested in future FYs.

#### FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

On March 25, 2004, the Department's STD Program submitted an Innovative, Developmental, Exploratory Awards (I.D.E.A) application to the UARP to receive funding to support a "Screening for Acute HIV Infection in High Risk Men in Los Angeles County" project. On October 6, 2004, the UARP completed its review of IDEA applications and informed the DHS STD Program under a letter of award that it found its proposed project meritorious and recommended it for funding. On July 14, 2005, the DHS' Institutional Review Board (IRB) approved the protocol to be followed for the project. On July 14, 2005, the DHS STD Program was informed of the IRB's approval of the protocol to be used under the project. On August 9, 2005, the UARP sent award Agreement No. ID04-LAC-028 to the DHS STD Program for approval.

To detect primary HIV infection, the project will use a Nucleic Acid Amplification Test (NAAT). NAAT Medical laboratory tests will be performed by the Department's Public Health Laboratory on specimens provided by the Los Angeles Gay and Lesbian Center. All clients will be informed of their HIV test results. Clients that are HIV antibody negative and NAAT positive will be called back for followup in order to verify HIV infection status.

Agreement No. ID04-LAC-028 (Exhibit I) has been reviewed and approved by County Counsel as to form.

Attachments A and B provide additional information. Attachment B is the Grants Management Statement which the Board instructed all County Departments to include in all Board letters for grants exceeding \$100,000.

The Honorable Board of Supervisors October 6, 2005 Page 3

# **CONTRACTING PROCESS:**

Not applicable. It is not appropriate to advertise the acceptance of grants awarded directly to the County's DHS on the Los Angeles (L.A.) County Online Web Site as a contract/business opportunity.

# **IMPACT ON CURRENT SERVICES (OR PROJECTS):**

Approval of the recommended action will assist the Department's STD Program in assessing the accuracy of HIV testing procedures.

When approved, the Department of Health Services requires three signed copies of the Board's action.

Respectfully submitted,

Thomas L. Garthwaite, M.D.

Director and Chief Medical Officer

TLG:gi

Attachments (3)

c: Chief Administrative Officer County Counsel Executive Officer, Board of Supervisors

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#### **SUMMARY OF AGREEMENT**

# 1. TYPE OF SERVICES:

Sexually Transmitted Disease Program project designed to improve early HIV diagnosis and related medical intervention.

# 2. AGENCY INFORMATION:

The Regents of the University of California Universitywide AIDS Research Program Office of Health Affairs 300 Lakeside Drive, 6th Floor Oakland, California 94612-3550

Attention: Susan Carter, J.D., Health Care Financing and Policy Research Administrator

Telephone: (510) 987-0702 Facsimile: (510) 835-4220

e-mail address: www.susancarter@ucop.edu

#### 3. TERM OF AGREEMENT(S):

June 1, 2005 through May 31, 2007.

# 4. FINANCIAL INFORMATION:

Total program costs to conduct the project is approximately \$166,237, offset by \$113,250 in fund from the Regents of the University of California - Universitywide AIDS Research Program and \$52,987 in DHS inkind medical laboratory testing resources. Funding is included in the Fiscal Year (FY) 2005-06 Adopted Budget and will be requested in future FYs.

# 5. GEOGRAPHIC AREA TO BE SERVED:

Countywide

# 6. <u>DESIGNATED ACCOUNTABLE FOR PROJECT MONITORING:</u>

Peter R. Kerndt, M.D., M.P.H., Director, Sexually Transmitted Disease Program

#### 7. APPROVALS:

Public Health: John F. Schunhoff, Ph.D., Chief of Operations

Contract and Grants Division: Cara O'Neill, Chief

County Counsel (approval as to form): Allison Morse, Deputy County Counsel

# Los Angeles County Chief Administrative Office Grant Management Statement for Grants Exceeding \$100,000

Department: Health	Services							
Grant Project Title and Description								
	cute HIV Infection in High Risk Men in smitted Disease (STD) Program project ntion.							
Funding Agency	ling Agency Program (Fed. Grant #/State Bill or Code #)			Grant Acceptance Deadline				
UARP	Agreement No. ID04-LAC-028	t No. ID04-LAC-028			Date of Board Approval			
Total Amount of Grant	\$113,250	County Match Req	uireme	nts	Non	e		
Grant Period:	Begin Date: 06/01/05	End Dat	-					
Number of Personnel H	fired Under this Grant: None	Full Time	0	Part		0		
	Obligations Imposed on the County	When the Grant E	<u>kpires</u>					
Will all personnel hired program?	I for this program be informed this is a	grant funded	Yes	X	No			
Will all personnel hired	for this program be placed on tempora	ary ("N") items?	Yes	X	No			
Is the County obligated	to continue this program after the gran	t expires	Yes		No	<u>X</u>		
If the County is not obligated to continue this program after the grant expires, the Department will:								
a). Absorb the program	n cost without reducing other services		Yes		No	X		
b). Identify other reven	nue sources		Yes	X	No	-		
Describe: Apply f	for other grants as appropriate.							
c). Eliminate or reduce grant.	e, as appropriate, positions/program cos	ets funded by this	Yes	X	No			
Impact of additional per	rsonnel on existing space: None					-		
Other requirements not	mentioned above None	11						
Department Head	Tol to		Dat	e //	1/5/	05-		

ID04-LAC-028 PI: Peter Kerndt, MD, MPH

# AGREEMENT NO. ID04-LAC-028 between THE REGENTS OF THE UNIVERSITY OF CALIFORNIA UNIVERSITYWIDE AIDS RESEARCH PROGRAM and LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES

THIS AGREEMENT is between The Regents of the University of California, (hereinafter called "The Regents") represented by the Office of the Vice President—Health Affairs, Universitywide AIDS Research Program (hereinafter called "UARP"), and Los Angeles County Department of Health Services (hereinafter called the "Recipient"), a non-profit institution.

#### WITNESS THAT

WHEREAS, the State of California Legislature has requested The Regents of the University of California establish and administer a program supporting research on Acquired Immune Deficiency Syndrome (AIDS); and

WHEREAS, the State of California has appropriated funds to The Regents for the administration of the Universitywide AIDS Research Program; and

WHEREAS, The Regents, in keeping with the outcome of a scientific peer review process and the advice of an appropriately constituted Scientific Advisory Committee, has recommended Recipient's proposal for the conduct of UARP research; and

WHEREAS, the Vice President for Health Affairs, acting on the recommendation of the Scientific Advisory Committee has approved Recipient's proposal for conducting UARP research,

NOW THEREFORE, the parties mutually agree as follows:

#### 1. STATEMENT OF WORK

Recipient shall conduct UARP research in accordance with its proposal entitled "Screening for Acute HIV Infection in High Risk Men in Los Angeles County" which is incorporated herein by reference.

#### 2. PERIOD OF PERFORMANCE

This Agreement shall be in effect from June 1, 2005 through May 31, 2007.

#### TECHNICAL DIRECTION

The performance of the work shall be under the direction of the Principal Investigator Peter Kerndt, MD, MPH. See the <u>Special Research Programs Grant Administration Manual</u>, which can be found at <a href="http://www.ucop.edu/srphome/uarp/">http://www.ucop.edu/srphome/uarp/</a> Grant%20Admin%20manual/welcome.html, for specific minimum percent effort and other requirements and actions requiring prior approval.

#### 4. BUDGET AND EXPENDITURES

- A. The total amount of funds made available and reimbursable to Recipient under this Agreement for the period starting June 1, 2005 through May 31, 2007 shall not exceed \$113,250. Expenditures shall be in accordance with the approved budgets, attached hereto as Exhibit A, and the rules and regulations detailed in the <a href="Special Research Programs Grant Administration Manual">Special Research Programs Grant Administration Manual</a>.
- B. In accordance with the <u>Special Research Programs Grant Administration Manual</u>, indirect costs are reimbursable for 25% of total direct costs, excluding equipment, or at the federally approved rate and base for Recipient institution (or other similarly established rate), whichever is less.

# 5. FISCAL AND ADMINISTRATIVE STANDARDS

Allowable costs and administration shall be governed by standards as set forth in this Agreement, the Special Research Programs Grant Administration Manual found on the internet at http://www.ucop.edu/srphome/uarp/Grant%20Admin%20manual/welcome.html, and Office of Management and Budget Circulars Nos. A-21 or A-122 as applicable, and A-110, in that order of precedence. (Note: Although funds used to support this Agreement are non-federal, reference to the OMB Circulars is included here to take advantage of established institutional practices and procedures.)

# 6. PAYMENT AND INVOICING

Payment for 80% of the amount listed in Article 4 will be released after execution of this Agreement by both parties, and clearance of the contingencies listed below. The remaining 20% will be paid after receipt of the final reports required by Articles 7 and 8. Invoices are not required at any stage.

Payments are contingent upon:

- Appropriation and availability of funds provided by the California State Legislature
- Execution of this Agreement by both parties. (Once, at initiation of this award.)
- Clearance of all administrative issues, such as Human/Animal Subjects Approvals. (Annually.)
- Receipt of all required reports (Fiscal and Scientific Progress reports as described in Articles 7 and 8.)

If sufficient funds are not appropriated for this program and Agreement, or if funding for any fiscal year is reduced or deleted, this Agreement shall either be cancelled, pursuant to the applicable Agreement termination provisions, or amended to reflect a reduction in funds.

# 7. FINANCIAL ACCOUNTING, RECORDS, REPORTS

- A. Recipient shall maintain accounts, records and other evidence pertaining to costs incurred.
- B. This Agreement shall be subject to the examination and audit of The Regents and the Auditor General of the State of California from the start date to three years after receipt of all required reports. The examination and audit shall be confined to those matters connected with the performance of this Agreement, including, but not limited to, the cost of administering the Agreement.
- C. Recipient shall submit annual fiscal reports to UARP, detailing its expenditures for the project within 90 days of each project year-end and within 90 days of expiration or termination of this Agreement. The format for the fiscal reports is described in the <u>Special Research Programs Grant Administration Manual</u>.

If a no-cost time extension is granted, an annual fiscal report must still be submitted within 90 days of the original termination date in addition to the final fiscal report due within 90 days of the new end date.

# 8. <u>SCIENTIFIC PROGRESS REPORT</u>

Annual scientific progress reports regarding the research supported hereunder shall be submitted to UARP 30 days prior to the end of each program year. The format for the progress report is described in the <u>Special Research Programs Grant Administration Manual</u>.

In the final year of this Agreement, the scientific report shall be submitted to UARP within 60 days after expiration or termination of this Agreement, whichever occurs first. If a no-cost time extension is granted, an annual progress report must still be submitted 30 days prior to the end of the program year, in addition to the final report due within 60 days of the new end date.

The Principal Investigator or his/her representative shall attend the UARP's annual meeting to report preliminary data and progress of work. An abstract of research findings to date for the annual meeting is due to the UARP prior to the meeting. The UARP will notify the Principal Investigator of the time and place of such meeting.

#### 9. PUBLICATION

Any publication resulting from the research supported by this Agreement must acknowledge such support. The wording to be used is "This research was supported by funds provided by the Universitywide AIDS Research Program, Grant Number ID04-LAC-028." One reprint of each publication shall be provided to the UARP.

#### 10. <u>TERMINATION</u>

This Agreement may be terminated in whole or in part without cause by either party upon 30 days prior written notice to the other party. The Regents shall reimburse Recipient for noncancellable obligations, and allowable and proper budgeted costs incurred to date of termination. Balances owed to Recipient will be paid upon receipt and acceptance of all final reports. Recipient shall take all necessary measures to mitigate its costs and shall return to The Regents all unliquidated advance payments within 90 days of termination.

#### 11. AMENDMENTS

Requests for No Cost Time Extensions, Carry-Forwards, Rebudgeting, and changes in Key Personnel may be approved by the UARP Program Official upon request by Recipient as described in the Special Research Programs Grant Administration Manual. All other amendments or modifications to this Agreement shall require execution on behalf of The Regents by the Director of Materiel Management and shall be by mutual consent of the parties in writing.

#### 12. INSURANCE

The Recipient at its sole cost and expense, shall insure its activities in connection with this Agreement and obtain, keep in force and maintain insurance as follows: or in the alternative provide evidence of self insurance.

A. Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

(a)	Each Occurrence	\$1,000,000
(b)	Products/Completed Operations Aggregate	\$1,000,000
(c)	Personal and Advertising Injury	\$1,000,000
(d)	General Aggregate	\$3,000,000

If the above insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement.

- B. Business Automobile Liability Insurance for owned, scheduled, non-owned, or hired automobiles with a combined single limit no less than one million (\$1,000,000) per occurrence if using automobiles in conducting research under this Agreement.
- C. Workers' Compensation as required under California State law.
- D. Professional Medical and Hospital Liability Insurance (contractual liability included) with limits of two million dollars (\$2,000,000) per occurrence and five million dollars (\$5,000,000) general aggregate.

If the above insurance is written on a claims-made form, it shall continue for three (3) years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement.

Note: Professional Medical and Hospital Liability Insurance is required only when healthcare professionals and/or health care students are involved in patient care under this agreement.

E. Commercial Blanket Bond with a limit not less than the amount of grant funds provided by this Agreement in Recipient's possession at any one time covering all employees of Recipient, including coverage to protect money and securities as found in a Comprehensive Crime Policy.

- F. Such other insurance in such amounts which from time to time may be reasonably required by the mutual consent of The Regents and the Recipient against other insurable risks relating to performance.
- G. The coverages required under this Article shall not in any way limit the liability of the Recipient.
- H. The coverages referred to under (A) and (B) of this Article shall include The Regents as an additional insured. Such a provision, however, shall apply only in proportion to and to the extent of the negligent acts or omissions of Recipient, its officers, employees, and agents. A thirty (30)-day advance written notice (10 days for non-payment of premium) to The Regents of any modification, change or cancellation of any of the above insurance coverages is required. Upon the execution of this Agreement, Recipient shall furnish The Regents with Certificates of Insurance evidencing compliance with all requirements.

# 13. <u>INDEMNIFICATION</u>

Recipient shall defend, indemnify, and hold The Regents, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorney's fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of Recipient, its officers, agents, or employees.

The Regents shall defend, indemnify, and hold Recipient, its officers, employees, and agents harmless from and against any all liability, loss, expense (including reasonable attorney's fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of The Regents, its officers, agents, or employees.

The Recipient covenants and warrants that the conduct of the research shall be in accord with all applicable federal and state regulations pertaining to the protection of human subjects, use of animal subjects, and handling of biohazard materials, and further covenants and warrants that approvals in these areas shall be secured from, and periodically reviewed by, a duly constituted institutional review committee for each relevant area.

# 14. PATENTS, COPYRIGHTS, AND RIGHTS IN DATA

- A. Confidentiality: Neither party shall furnish any information considered enabling and confidential or proprietary by it or by any third parties to the other party in connection with this Agreement, absent a subsequent and separate written agreement between the parties to the contrary.
- B. Patent Rights: All rights to any patentable inventions or discoveries conceived or reduced to practice in the performance of the work conducted under this Agreement shall belong to the Recipient.
- C. Copyrights: All rights in copyright works created by the Recipient in the performance of work under this Agreement are the property of the Recipient. To the extent that the Recipient shall have the legal right to do so, the Recipient grants The Regents a royalty-free, non-exclusive, nontransferable, irrevocable license to reproduce, prepare derivative works, and distribute copies of the deliverables specified in the Scope of Work for educational and non-commercial research purposes and to have or permit others to do so on its behalf.
- D. Upon request, Recipient shall provide The Regents with access to any data utilized in the performance of work under this Agreement.
- E. Tangible Research Results: Other discoveries made or reduced to practice under this Agreement which may not be protectable by patent or copyright, such as biological materials, plasmids, and cell lines, shall be the property of the Recipient and licensed in the public interest.
- F. Commercial Application and Reporting: The Recipient shall use reasonable efforts to achieve expeditious practical application of the patents, copyrights, and tangible research results developed in the course of the performance of work under this Agreement. Annual and final technical reports shall include a description on the commercial utilization of the research results or on the efforts at obtaining such utilization, including providing non-confidential,

non-enabling information regarding any invention or discovery and patent applications filed or patents issued thereon.

# 15. AFFIRMATIVE ACTION/NON-DISCRIMINATION

Recipient agrees that when applicable, the following are incorporated herein as though set forth in full: the nondiscrimination and affirmative action clauses contained in Executive Order 11246, as amended, relative to equal employment opportunity for all persons without regard to race, color, religion, sex or national origin, and the implementing rules and regulations contained in Title 41, part 60 of the Code of Federal Regulations, as amended; the non-discrimination and affirmative action clause contained in Section 503 of the Rehabilitation Act of 1973, as amended, relative to the employment and advancement in employment of qualified individual(s) with a disability without discrimination, and the implementing rules and regulations in Title 41, part 60-741 of the Code of Federal Regulations; the non-discrimination and affirmative action clause of the Vietnam Era Veterans Readjustment Assistance Act of 1974 relative to the employment and advancement in employment of qualified special disabled veterans, recently separated Vietnam era veterans, and veterans who served on active duty during a war or in a campaign or expedition for which a campaign badge has been authorized, without discrimination, and the implementing rules and regulations in Title 41, part 60-250 of the Code of Federal Regulations; and the non-discrimination clause required by California Government Code Section 12990 relative to equal employment opportunity for all persons without regard to race, religious creed, color, national origin, ancestry, physical or mental disability, medical condition (cancer-related or genetic characteristics), marital status, sex, age, or sexual orientation, and the implementing rules and regulations of Title 2, Division 4, Chapter 5 of the California Code of Regulations.

#### 16. TITLE TO PROPERTY

Equipment is defined as non-expendable, tangible, personal property which has an acquisition cost of \$1,500 or more, is free standing, and has a normal life expectancy of one year or more. The Regents reserve the right to transfer title to equipment to The Regents or to a third party named by The Regents. The Regents shall notify the Recipient within 120 days from expiration of this Agreement of its intention to transfer title; otherwise title to equipment shall remain with the Recipient.

Expendable personal property will become property of the Recipient.

#### 17. INDEPENDENT CONTRACTOR

Recipient and its employees, consultants, agents, or independent contractors will perform all services under this Agreement as independent contractors. Nothing in this Agreement will be deemed to create an employer-employee or principal-agent relationship between Regents and Recipient's employees, consultants, agents, or independent contractors. Recipient and its employees, consultants, agents and lower tier subawardees will not, by virtue of any services provided under this Agreement, be entitled to participate, as an employee or otherwise, in or under any employee benefit plan of Regents or any employment right or benefit available to or enjoyed by employees of Regents.

# 18. PROJECT PERSONNEL AND OTHER INFORMATION

#### THE REGENTS

Program and Fiscal Matters:

Susan Carter, JD (510) 987-0720 Universitywide AIDS Research Program Office of Health Affairs Office of the President University of California 300 Lakeside Drive, 6th Floor Oakland, CA 94612-3550

# ID04-LAC-028 PI: Peter Kerndt, MD, MPH

1111 Franklin St., 7th Floor Oakland, CA 94607-5200 **RECIPIENT** Program Matters: Peter Kerndt, M.D., M.P.H. Title <u>Director</u>, <u>STD Program LA County</u>, Public Health Address 2615 S. Grand Avenue, Room 500, 5th Floor Los Angeles, CA 90007 Phone (213) 744-3093 Fiscal Matters: Name Belinda Snguon Title Acting Grants Manager Address 5555 Ferguson Drive, Room 100-50 Commerce, CA 90022 Phone (323) 890-7836 Contractual Matters: Jacqueline Battle Name Title Director, Administrative Services Address 2615 S. Grand Avenue, Room 500, 5th Floor Los Angeles, CA 90022 Phone (213) 744-3116 PLEASE INSERT RECIPIENT'S FEDERAL IDENTIFICATION NO. 099-446254 IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized

**SERVICES** 

By:

Name:

Lourdes DeMattos

Contract and Grant Officer Research Administration Office University of California

(510) 987-9850

LOS ANGELES COUNTY DEPARTMENT OF HEALTH

Contractual Matters:

representatives.

OF CALIFORNIA

Name: Stuart P. Davis

Date:

THE REGENTS OF THE UNIVERSITY

Title: Director, Strategic Sourcing